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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HENDRICKS, KEITH D

ART UNIT	PAPER NUMBER
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1761

DATE MAILED: 12/10/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 10/041,080		Applicant(s) ASHIE ET AL.	
Examiner Keith Hendricks		Art Unit 1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-15,17-19 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3-15,17-19 and 21-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Priority

i) Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: The paragraph at page 5, lines 18-20 of the specification. While bovine chymosin was claimed in the parent application, the information regarding commercial availability and preferred source of the enzyme was not provided in the original parent application, 09/620,494.

This second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ 2d 1077 (Fed. Cir. 1994).

ii) This application repeats a substantial portion of prior Application No. 09/620,494, filed July 20, 2000, and adds additional disclosure not presented in the prior application. See page 5, lines 18-20. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Appropriate correction is required. Applicant is cautioned against the introduction of new matter to the original disclosure, including deletion of essential subject matter that may affect the claims.

Specification

The disclosure is objected to because of the following informalities:

i) This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

ii) Page 5, line 20 recites a source of bovine chymosin as "... e.g. Chris Hansen, Inc. _____", but the information is incomplete. Correction of the specification is required.

Claim Objections

Claim 10 is objected to because of the following informalities: it is dependent upon itself (claim 10). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase “is defined as”, is vague and confusing. Initially, it is unclear as to how such a “definition” of a term (“limited substrate specificity”) may change repeatedly within the claims. Secondly, this does not provide a positive, active method step, or property, of the claimed invention. Further, it is unclear as to who is responsible for “defining” the specificity of the enzyme, and if this is the same as the clear standard definition of an enzyme’s activity and specificity, as accepted in the art and set forth in *Enzyme Nomenclature*, 1992. Apart from well-known, art-accepted definitions, the claims and specification are charged with the duty to clearly point out and distinctly claim applicants’ invention. To this point, the following is a quotation of the first paragraph of 35 U.S.C. 112: The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The phrase “only one of two of the major protein components of meat” is indefinite for the following reasons:

- It is unclear where in the specification that applicants have support for limiting the claims to the use of an enzyme which hydrolyzes “only one” of the meat proteins. At best, at page 4, lines 28-29, states that the enzymes may “digest either or both”. However, the claim does not provide a clear, precise description of the claimed invention, such that one skilled in the art would recognize to which “one” protein applicant refers, in order to select an enzyme encompassed by the claims.

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- The “two of the major protein components of meat” are not defined by the claims or specification, such that one skilled in the art would recognize which “one” protein is intended. At best, page 2 of the specification describes “connective tissue/collagen” and “myofibrillar proteins” as “*the* major meat proteins”. These are not described as “two *of* the”.
- Further, as is well-known and defined in the art, muscle fibers (myofibrillar proteins) are composed of three proteins: myosin, actin and tropomyosin. It is unclear if the enzyme activity claimed is to act on any or all of these subsets of “two of the major protein components of meat”.

Claims 22-24 and 26-28 are indefinite for the recitation of the degree of hydrolysis as “definition” of an enzyme’s specificity. Degree of hydrolysis (DH) is a measure of the results of the hydrolysis reaction of an enzyme, which is a function of the reaction time, temperature, pH, substrate utilized and other environmental factors. However, “limited substrate specificity” is defined in the art by the “limited” ability of an enzyme to act upon certain particular substrates, but not others. It is not defined by the degree to which an enzyme may act upon a single particular substrate, i.e. the DH. If an enzyme is able to act upon a substrate, the enzyme reaction will continue until it reaches equilibrium, runs out of substrate, or is interrupted by outside factors, such as those described above. If the reaction is halted by an increase in temperature, for example, then the degree to which the enzyme hydrolyzed the substrate would be dependent upon, and a direct factor of, the time to which it was allowed to act, not because it suddenly became incapable of hydrolyzing the substrate (i.e. changed it’s inherent “substrate specificity”).

Thus, applicants claims 22-24 and 26-28 do not serve to clearly define applicants’ invention.

Claims 25-28 are indefinite for the recitation of “the method of claim 15”. Claim 15 is directed to a composition.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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i) Claims 1, 10, 13 and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Paulin (EP 0 362 177, of record).

Paulin discloses the use of a "heat sensitive enzyme", i.e. a fungal thermolabile protease, in a method of tenderizing and processing meats. The enzyme is added directly to the meat. The particular fungal protease shown is known in the art as having the "limited substrate specificity" of an aspartic endopeptidase. In example 1, the meat and enzyme are mixed, and then filled into tins, thus reading upon the "tumbling" of instant claim 10 (included herein, as it is unclear from which claim it depends). Thus, the claimed invention is anticipated by the reference.

It is noted that the recitations of new claims 21-24 do not necessarily limit the particular enzyme or source of enzyme, *per se*. This is especially true, where the claims do not state that the meat proteins are digested to a particular degree of hydrolysis, but rather simply that the activity ("limited substrate specificity") of the enzyme is "defined as" a digestion to a particular degree of hydrolysis. See also page 4, line 28 – page 5, line 1, of the specification, where it is stated that the proteases (plural) "include, without limitation, those that" possess the ability to digest "either or both of the meat protein components" to a particular DH. Thus, absent any clear and convincing evidence or arguments to the contrary, the referenced enzyme possesses this property, as it hydrolyzes the meat proteins contained therein.

ii) Claims 1, 3-15, 17-19 and 21-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Wistreich et al.

Wistreich et al. disclose a method of producing sausages, by adding both a "powdered milk and powdered enzyme capable of precipitating proteins when both are in an aqueous medium" (col. 1). A preferred enzyme is rennin (aka chymosin. See attached Bender et al., Dictionary of Nutrition and Food Technology), or "pepsin, trypsin, papain, bromelin, ficin and the like". The milk solids and enzyme "may be added separately or as a premixed composition", and "an aqueous concentrate of enzyme may be added at a subsequent stage of the processing" (col. 2). The meat may either be raw or cured, and additional ingredients may be included in the composition. Such ingredients including curing agents like salts and nitrites (col. 2, and examples), spices and seasonings. As the instant claims "comprise" certain steps and ingredients, they read upon the disclosed methods and compositions as described above. For example, the claims do not exclude the use of milk solids in addition to the bovine chymosin protease, and the specification does not appear to provide support for claims limited otherwise.

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It is noted that the recitations of new claims 21-28 do not necessarily limit the particular enzyme or source of enzyme, *per se*. This is especially true, where the claims do not state that the meat proteins are digested to a particular degree of hydrolysis, but rather simply that the activity ("limited substrate specificity") of the enzyme is "defined as" a digestion to a particular degree of hydrolysis. See also page 4, line 28 – page 5, line 1, of the specification, where it is stated that the proteases (plural) "include, without limitation, those that" possess the ability to digest "either or both of the meat protein components" to a particular DH. Thus, absent any clear and convincing evidence or arguments to the contrary, the referenced enzyme possesses this property, as it hydrolyzes the meat proteins contained therein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

i) Claims 1, 3-4, 10, 7-14 and 21-24 are rejected under **35 U.S.C. 102(b)** as being anticipated by, or in the alternative, are rejected under **35 U.S.C. 103(a)** as being unpatentable over Robbins et al. (US PAT 4,600,589).

Robbins et al. discloses a method of meat tenderization using a protease from *Trichoderma reesei*. "The enzyme is an aspartic acid protease with proteolytic properties similar to the animal protease, cathepsin D. The enzyme acts selectively upon the myofibrillar proteins of meat producing a desirable uniform texture" (abstract). At column 1, it is stated that meat has been treated with cathepsin D from bovine spleen extract, which produced structural changes in the meat common to tenderized muscle. Although the reference does not specifically state the conditions or relative amounts of the cathepsin D utilizes, it provides such information for the similarly-active protease from *T. reesei*. Fresh or freeze-dried meat (col. 2) may be marinated or injected for tenderization (col. 6); amounts of protease are provided, for example, at columns 5-6; Table 1 shows that meat treated with said enzyme activity demonstrates approximately 77% shear force relative to the untreated meat. In the examples, the meat and enzyme are mixed, thus reading upon the "tumbling" of instant claim 10 (included herein, as it is

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unclear from which claim it depends). As the reference discloses meat tenderization utilizing the *T. reesei* protease, alternatively, the particular amounts and resultant properties would have been obvious to one of ordinary skill in the art for that of the bovine cathepsin D protease, as well.

It is noted that the recitations of new claims 21-24 do not necessarily limit the particular enzyme or source of enzyme, *per se*. This is especially true, where the claims do not state that the meat proteins are digested to a particular degree of hydrolysis, but rather simply that the activity ("limited substrate specificity") of the enzyme is "defined as" a digestion to a particular degree of hydrolysis. See also page 4, line 28 – page 5, line 1, of the specification, where it is stated that the proteases (plural) "include, without limitation, those that" possess the ability to digest "either or both of the meat protein components" to a particular DH. Thus, absent any clear and convincing evidence or arguments to the contrary, the referenced enzyme possesses this property, as it hydrolyzes the meat proteins contained therein.

ii) Claims 3-9, 11-12, 14-19 and 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paulin, in view of Wistreich et al., as evidenced by Bender et al. (Dictionary of Nutrition and Food Technology).

Wistreich et al. is taken as cited above.

Paulin is taken as cited above. Further, the reference teaches that other heat-sensitive proteases from "animal, vegetable or microbial origin", may be utilized (pg. 3, 5). "The maximum effect is provided by rennet" (pg. 3, 5).

Bender et al. show that rennet is an "extract of calf stomach" containing rennin, and that rennin is an enzyme also known as chymosin.

As the use of chymosin (aka rennin, or rennet) with meat products was known in the art, as shown by Wistreich et al. for sausage meat products, and since Paulin et al. directly suggest the use of other heat-sensitive proteases from "animal, vegetable or microbial origin", where "the maximum effect is provided by rennet", it would have been obvious to one of ordinary skill in the art to have utilized the bovine proteolytic enzyme, chymosin, within known meat processing and tenderization methods, such as those of Paulin.

It is noted that the recitations of new claims 21-28 do not necessarily limit the particular enzyme or source of enzyme, *per se*. This is especially true, where the claims do not state that the meat proteins are digested to a particular degree of hydrolysis, but rather simply that the activity ("limited substrate specificity") of the enzyme is "defined as" a digestion to a particular degree of hydrolysis. See also page

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4, line 28 – page 5, line 1, of the specification, where it is stated that the proteases (plural) “include, without limitation, those that” possess the ability to digest “either or both of the meat protein components” to a particular DH. Thus, absent any clear and convincing evidence or arguments to the contrary, the referenced enzyme possesses this property, as it hydrolyzes the meat proteins contained therein.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 10, 13 and 21-24 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-22 of U. S. Patent No. 6,149,950. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass the use of a thermolabile protease within meat tenderization methods and compositions.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano, can be reached at (703) 308-3959. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3602.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


KEITH HENDRICKS
PRIMARY EXAMINER